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OFFICE OF
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SUBSTANCES

MEMORANDUM

SUBJECT: Decisions on the Ecological, Fate, and Effects Task Force

FROM: Linda J. Fisher
Assistant Administrator

TO: Douglas Campt, Director
Office of Pesticide Programs

In May 1992, I initiated the Ecological, Fate and Effects Task Force to evaluate the testing requirements for ecological and environmental fate with respect to their impact upon OPP's regulatory programs. For the past several months, numerous OPP managers and analysts, as well as participants from OPPE, OPPT, OGC, and ORD have put an extraordinary amount of time and effort into this workgroup. These decisions, once implemented, will result in protective and timely decisions in the area of ecological risk management. The attached document outlines the specific decisions on the very important issues of ecological risk management raised by the Task Force. There are still many details to resolve as this new paradigm is implemented. I have asked Deputy Assistant Administrator Vic Kimm to chair an implementation committee.

The effort put into the Task Force deliberations was clearly monumental. The Program showed a remarkable commitment to analyzing and addressing these issues. In addition, the support provided by OPPT, OPPE, ORD, and OGC was outstanding, as were their contributions to our policy discussions.

The principle issue addressed by the Task Force is the effect of the data generated from OPP's ecological and environmental fate data requirements on the Reregistration program. As a regulatory agency, we must have a clear sense of how to use the data which we require. The value added by these data on regulatory decisions (registration and reregistration) was carefully reviewed. Secondly, the Task Force evaluated the effect of collecting and reviewing ecological and environmental fate data on the legislative deadlines established for reregistration. Although the Task Force focused much of its attention on reregistration, many of its findings apply to the registration program.

In our registration and reregistration programs, the Agency is interested in setting risk based priorities and making protective decisions in a timely fashion. We must recognize that registration is a continuous process. Registration decisions and reregistration decisions made under FIFRA 88 may be revisited in following years as we learn more about ecological risk.

In summary, regulatory managers will attempt to make decisions regarding ecological risk earlier in the data gathering process, often with less data than are currently required. Decisions should be made in the absence of the higher tiered data requirements whenever possible. In addition to making decisions earlier in the data gathering process, OPP will rely much more extensively on risk mitigation for ecological effects when information indicates that some "level of concern" has been exceeded.

More specifically, OPP will no longer require avian and aquatic field testing, except in unusual circumstances. Rather, decisions will be based on lab testing, incident data and other information which can easily be collected to enable the program to better characterize potential risk. Ground water monitoring studies will be required only if risk managers believe that the existing groundwater database, including modeling analyses, do not provide an adequate basis for up-front regulatory decisions. Finally, the Agency will begin to develop a longer-term strategy for obtaining information needed to reduce uncertainty in evaluating ecological risk associated with long-term effects of pesticide use.

The decisions outlined here will tremendously improve our ability to meet the deadlines established for reregistration in FIFRA 88, and to evaluate registration actions in a more timely fashion. More importantly, I believe these changes will result in a significant and prompt improvement in environmental quality. More decisions -- environmentally protective decisions, with a major focus on up-front remediation where appropriate -- will be made with far greater speed under the new paradigm than would have ever been feasible under the existing testing scheme.

Our work has only begun. We now must develop a detailed implementation plan to carry out this new paradigm. This plan should include specific process changes with respect to both registration and reregistration, disposition of existing data call-ins (DCIs) which are affected by this effort, development of a process for risk mitigation, and specific internal procedures to ensure the exposure estimates and the estimated environmental concentrations (EECs) are calculated using appropriate modelling and actual field data when feasible. Clearly, there are numerous

issues which will need to be addressed, beyond those identified here, in the implementation plan. It is my goal to have a final implementation plan by January 5, 1993.

Again, I wish to thank you and your staff for the commitment you have brought to this very important effort.

ATTACHMENT: Program Guidance on Ecological Risk Management

I. AQUATIC (mesocosms)

1. Assistant Administrator (AA) Decision

The AA supports the workgroup recommendation to make regulatory decisions on aquatic risk in the absence of the mesocosm studies. Reregistration, Registration, and Special Review decisions over the course of Reregistration will be based upon information available from laboratory studies, published information, and incident data. Regulatory decisions will be based on the effects, both acute and chronic, of pesticide use on several aquatic species (warm water fish, cold water fish, marine fish, invertebrates, estuarine/marine mollusks, and estuarine/marine shrimp). Although the Agency believes that long-term, indirect effects of pesticide use on aquatic ecosystems may be important, the Agency does not have a testing scheme in place to accurately measure such effects within the time specified for Reregistration. For policy reasons, the Agency has defined a set of regulatory endpoints for reregistration purposes. As we develop a better understanding of these endpoints, such as the indirect effects of pesticide use on aquatic ecosystems, the Agency reserves the right to regulate against such endpoints in the registration program in the future.

OPP will begin to develop a strategy for making regulatory decisions on the long-term ecological effects of pesticide use. In this effort, OPP should consider a longer time frame for field studies as well as the possibility of testing a single representative of a class of pesticides. The current field studies have a duration of about two years and are performed on a chemical by chemical basis. These studies do not provide risk managers with information which greatly enhances the risk management decision-making process.

For future reregistration and registration purposes, OPP should use risk mitigation to the extent feasible to achieve acceptable risk. Risk mitigation includes all practices which reduce hazard or exposure. Mitigation can be in the form of reduced application rates, mandatory tillage practices or a change in the pesticide's formulation, to name a few. With respect to the current aquatic triggers or "levels of concern", the AA supports the workgroup's recommendation to continue using the existing triggers. However, risk assessments should include a small stream as the receiving body of water. Risk management decisions should be based on the effects to flowing bodies of water unless a risk case, on a use specific basis, can be made as to the relevance of protecting small, closed water systems (such as a pond, wetland, or a small lake).

2. Levels of Concern

ACUTE:

If the EEC > 1/2LC50 (LC50 as measured for the most sensitive species)(EEC is estimated environmental concentration; LC50 is the lethal concentration which kills 50% of the test species), the aquatic risk of a pesticide is deemed to be of high concern, and may warrant regulatory action in addition to restricted use classification.

If 1/10 LC50 <= EEC <= 1/2LC50, then the pesticide is considered for classification as a restricted use pesticide.

If EEC < 1/10LC50, then the pesticide has low aquatic risk and no additional regulatory action will be pursued.

CHRONIC:

For both the Chronic Aquatic Invertebrate and Fish tests and the Life Cycle Fish tests, the level of concern is reached if the EEC >= LEL (LEL is the lowest effect level). These are both reproductive tests.

QUALITATIVE FACTORS:

Incident reports of fish kills trigger a level of concern. Availability of alternatives should be reviewed.

3. Effect on Reregistration

How will this policy change affect decision-making in the reregistration program? OPP will make regulatory decisions for aquatic risk following the guidelines established in the Levels of Concern (LOC) project. If a risk exceeds the LOC, the risk assessment should be refined using standard approaches such as application of more sophisticated models to estimate exposure and the EEC. If the LOC exceedance is supported, risk managers should require or negotiate risk reduction measures. It may be necessary to calculate the cost of mitigation in a very crude form prior to negotiating risk mitigation. This will help the Agency decision makers to make better informed decisions regarding mitigation measures to pursue in discussions with registrants. If the LOC is still exceeded after risk reduction measures are evaluated, a risk/benefit based decision, leading to specific regulatory determination, is necessary. A risk/benefit determination is necessary at this point because the concept of "acceptable risk" takes into consideration benefits. Thus acceptable risk may exceed the level of concern, and cannot be defined with a simple numerical standard. To define acceptable risk, a preliminary benefits assessment must be conducted. If it becomes clear that an in depth review of the risks and benefits is necessary to make a determination, then the chemical will be declared ineligible for reregistration, pending a Special Review or other regulatory action.

For purposes of risk characterization, OPP will evaluate the following parameters, which are viewed by the AA as essential pieces of information in making regulatory decisions in the area of aquatic risk. 1) The extent of use; 2) The environmental fate of the chemical; 3) The quality of the water body and surrounding use areas as habitat; 4) The species exposed; 5) incident reports of fish (or other aquatic species) kills; and, 6) availability of substitutes, including biological controls and integrated pest management. Each of these provides important qualitative or quantitative information to the risk manager.

Evaluating the risk reduction measures will be an important new step in this process. The final RED (Reregistration Eligibility Document) decision will rely significantly on EFED's (Environmental Fate and Effects Division) ability to evaluate proposed risk mitigation in a timely fashion. SRRD (Special Review and Reregistration Division) will also be required to make risk/benefit based reregistration decisions, often with uncertainties. OPP may need to consider the feasibility of follow-up residue monitoring to ensure that risk mitigation is successful. SRRD must continuously evaluate the contribution of additional information with respect to their ability to make decisions. New information should only be required when it significantly improves our ability to evaluate the risks and benefits of a pesticide.

4. Status of Mesocosm DCIs (Data Call-Ins)

At this point, complete, acceptable mesocosms will not normally be required for purposes of regulatory decision making (reregistration or registration), as these studies do not generally provide regulatory managers with information to make better regulatory decisions. RED decisions can and should be made in the absence of mesocosm studies. If SRRD or RD (Registration Division) feel that a regulatory decision cannot be made in the absence of an aquatic field study, the mesocosm can be required. OPP will continue to accept mesocosm studies which registrants submit to the Agency. These studies will be evaluated and used as confirmatory information in the aquatic risk assessment to the extent that the mesocosm provides relevant information with respect to the aquatic levels of concern. If the registrant believes that a mesocosm will refute a presumption of risk, they can pursue such a study. However, the Agency does not need to wait for such a study before making regulatory decisions.

5. Future Directions in Aquatic Risk Assessment/ Risk Management

Over the next five to ten years (period of FIFRA 88 reregistration) OPP should aim to greatly reduce the direct acute and chronic risks to aquatic environments. During that timeframe, OPP should develop a regulatory scheme for protecting aquatic ecosystems from the long-term effects of pesticide use based upon

improvements in our evolving scientific understanding of ecosystems. This may include the development of a long-term, mesocosm-like study, or actual residue monitoring of water bodies. OPP should evaluate all options which provide the Agency with the type of information which will allow us to make future regulatory decisions in a cost-effective manner.

II. AVIAN

1. AA Decision

The AA agrees with the workgroup conclusion that the avian field study provides very limited new information to an avian risk assessment, and that such field studies confirm the results of the lab studies. Except in unusual circumstances, where the value of an avian field study to a regulatory decision maker is significant, the avian field studies will no longer be required for purposes of reregistration and registration of individual active ingredients.

2. Levels of Concern

ACUTE:

If the EEC > 1/2 LC50, or the LD50/sqft > 1/2, the avian risk of a pesticide is deemed to be of high concern, and may warrant regulatory action in addition to restricted use classification.

If 1/5LC50 <= EEC <= 1/2LC50, then the pesticide is considered for classification as a restricted use pesticide.

If EEC < 1/5LC50, then the pesticide has low avian risk and no additional regulatory action will be pursued.

CHRONIC:

For chronic avian tests, the level of concern is reached if the EEC >= LEL.

Qualitative Factors: Incident reports play a critical role in the avian risk management process. Also important are extent of use, proximity to high value habitat, the fate of the chemical, the species exposed, and the availability of safer substitutes.

3. Effect on Reregistration

RED decisions will be made in the absence of avian field studies. If the chemical exceeds a level of concern for an avian endpoint, OPP will follow the same basic framework as for aquatic risk management. First, OPP will refine its hazard and exposure calculations. Secondly, OPP will evaluate risk reduction techniques (including the costs of mitigation). If mitigation is

insufficient to reduce the risk to below the level of concern, a preliminary benefits assessment will be performed and a risk/ benefit determination will be made. Although the level of concern identifies a point at which the Agency is unable to dismiss potential risks, it does not define either acceptable risk or the standard by which final risk-benefit determinations will be judged.

As stated in previous avian decisions, the Agency will not accept widespread and repeated avian mortality in the face of minor economic benefits to society. The "widespread and repeated" standard can be met on a local or regional as well as a national basis. As the economic benefits of a chemical increase, the standard for significant regulatory action is higher. For example, significant economic benefits may not be outweighed by risks unless those risks are very high, very widespread, or involve especially valued species or habitat.

For purposes of risk characterization, OPP will evaluate the following parameters, which are viewed by the AA as essential pieces of information in making regulatory decisions in the area of avian risk. 1) The extent of use (acreage); 2) The environmental fate of the chemical; 3) The quality of the crop and surrounding use areas as habitat (wildlife utilization); 4) The species exposed; 5) incident reports of bird kills; and, 6) availability of substitutes, including biological controls and integrated pest management. Each of these provides important

qualitative or quantitative information to the risk manager.

4. Status of Avian Field Studies DCIs

Avian field studies will not be required for a substantially complete data base except in highly unusual circumstances (the regulatory management divisions are unable to make a regulatory decision in the absence of such a study). Thus registrants will not be required to complete such studies.

5. Future Directions in Avian Risk Assessment/ Risk Management

OPP needs to develop a long-term strategy for improving the scientific risk assessment methodologies, building on findings of the most recent avian risk dialogue group. In addition, OPP should begin to evaluate the viability and usefulness of longer term avian monitoring in high use areas as well as a research plan for better understanding the impacts of pesticide use on birds.

Avian and aquatic levels of concern (acute and chronic) have been established in regulation and guidance over the last 10 to 15 years. As far as the Agency knows, these levels are appropriate, and OPP should continue to use these "triggers" for regulatory purposes. As a normal part of the scientific and regulatory process, these numbers will be subject to periodic review.

III. GROUND WATER

1. AA Decision

The AA supports making an explicit risk management decision before requiring a small scale prospective ground water monitoring study. The current practice is to require a small scale study if the chemical proves to be mobile and persistent, as determined by lab studies and a field dissipation study. There is a high level of confidence in the prospective ground water monitoring study from a scientific as well as a regulatory perspective. These studies can provide valuable information to regulatory managers in the protection of ground water from problem pesticides. As with all studies which the Agency requires, we should have a clear sense of how we will use the information, in a regulatory context, which the study will provide.

2. Levels of Concern

Mobility is defined as Kd <= 5 Mg/gm or Koc <=500 Mg/gm, or detection of the compound 90 cm in the soil profile in the soil dissipation study, and;

Persistence is defined as a soil half-life greater than 2-3 weeks, and;

A risk based (human health or ecological) trigger is exceeded, or has a high potential to be exceeded, ((OPP is currently working to define this trigger based on some fraction of a Maximum Contaminant Level (MCL) or Health Advisory (HA), and as appropriate, frequency of detections in high use areas).

3. Effect on Reregistration

The new process will involve a risk management decision before requiring the monitoring study. The following steps will be followed in the risk management process:

1) Determine if there is a known human health or environmental concern with the compound. If not, do not require the monitoring study, if so, go to 2);
2) evaluate the likelihood of the compound reaching a level of concern in a vulnerable area, given the entire data base of the compound (lab data, other monitoring, modelling, etc...); if it appears unlikely that the compound will reach ground water at a level of concern, do not require the monitoring study, if it appears feasible or likely, go to 3);
3) if the existing evidence indicates that a pesticide exceeds the Agency's threshold (level of concern), then regulate without the monitoring study; if the evidence is equivocal, then go to 4);

4) if possible, identify mitigation measures which will reduce or eliminate the Agency's concerns, and then negotiate or require such measures as a condition for registration/reregistration; consider requiring monitoring in high use areas to evaluate mitigation measures over time;
5) if mitigation is not feasible or the registrant and the Agency cannot agree on feasible measures, either require the monitoring study or regulate based on existing information.

A separate workgroup within OPP is identifying the levels at which various regulatory actions are to be taken. The ground water workgroup will develop a logical, risk based hierarchy of regulatory actions based upon levels of concern. Issues the workgroup will address include the following: What is the level of concern for a label advisory? Restricted Use classification? Risk mitigation or other regulatory restrictions? Under what conditions will we propose a State Management Plan?

The AA understands that for registration purposes, there will be little or no existing monitoring data to guide OPP in making a determination about the potential of a chemical reaching groundwater. Thus the need for a prospective monitoring study for registration purposes may be greater than it will be for reregistration purposes, due to the greater level of uncertainty.

4. Status of Existing Monitoring DCIs

OPP should perform a cursory review of the 45 chemicals which already have ground water monitoring DCIs to determine if a regulatory decision could be made in the absence of such studies. In particular, if the existing data base on a chemical indicates that regulatory action is warranted, we should pursue such action, and classify the monitoring study as optional. Where such studies are submitted to OPP, they should be evaluated and considered confirmatory. For chemicals which do not have a ground water DCI, we should go through the five step process outlined above.

IV. RISK MITIGATION

1. AA Decision

The Assistant Administrator fully supports the concept of using risk mitigation for pesticides which pose risks of concern. Over the next few weeks, OPP should develop a process which details how and when mitigation will be used. Of greatest importance should be how the program will evaluate risk reduction measures. This plan should also identify where in the risk management process mitigation will be imposed as well as who should be responsible for identifying appropriate measures. For both avian and aquatic risk mitigation, OPP should consider post-mitigation monitoring to evaluate the effectiveness of the mitigation measures.

Risk mitigation should be considered whenever a level of concern is exceeded to reduce exposure or hazard and provide added protection for the environment at the earliest possible time.

V. EXPOSURE, FATE AND ESTIMATED ENVIRONMENTAL CONCENTRATIONS

1. AA Decisions

The Assistant Administrator strongly supports efforts to move toward more realistic exposure estimates based on the most realistic and sophisticated EEC calculations using our most qualified personnel and employing the best available data and modeling techniques. In addition, OPP should use actual residue data in its ecological risk assessments whenever possible. Kenaga data should be used only when appropriate actual residue information are not available. OPP should evaluate the possibility of enhancing its existing residue chemistry data requirements to include the type of residue data used in ecological risk assessments.

VI. RISK MANAGER - RISK ASSESSOR INTERACTION

1. AA Decisions

The Assistant Administrator concurs with the workgroup's findings that there is a lack of guiding principles, objectives and

policies to guide risk assessment and risk management in the ecological area. This document should serve as a first step in providing such guidance. In addition, the Assistant Administrator finds that the roles of the risk assessors and risk managers in the area of ecological effects are not as clearly defined or well understood as they should be. OPP should begin to work through the recommended options with respect to risk assessment/ risk management interaction which are identified in the risk assessment/ risk management chapter.

VII. IMPLEMENTATION

OPP should develop a workplan which describes the process by which these decisions will be implemented. An implementation plan should be in final form by January 5, 1993. An implementation committee should operate under the direction of the Deputy Assistant Administrator of OPPTS. A preliminary plan and schedule should be presented to the AA by December, 1992. In the interim, program managers should strongly consider the direction of this guidance when making regulatory decisions in the areas of ecological risk management and assessment.